

United States Court of Appeals for the Federal Circuit

03-1201

MONSANTO COMPANY,

Plaintiff-Appellee,

v.

BAYER BIOSCIENCE N.V.
(formerly known as Aventis CropScience N.V.)

Defendant-Appellant.

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Appealed from: United States District Court for the Eastern District of Missouri

Judge E. Richard Webber

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DECIDED: March 30, 2004

Before NEWMAN, BRYSON, and PROST, Circuit Judges.

BRYSON, Circuit Judge.

Monsanto Company filed an action in the United States District Court for the Eastern District of Missouri, No. 4:00CV1915, seeking a declaratory judgment that its transgenic corn products did not infringe four patents owned by Aventis CropScience N.V., a predecessor of appellant Bayer BioScience N.V. The patents at issue claim a variety of methods and products relating to the insertion of bacterial DNA into plants to give the plants resistance to certain insects. Besides contending that it did not infringe any of the four patents, Monsanto alleged that the four patents were unenforceable and that various claims of the patents were invalid. Aventis counterclaimed, alleging that Monsanto infringed certain claims of each of the four patents.

I

The bacterium Bacillus thuringiensis (“Bt”) produces a protein that is toxic to certain insects.

Plant Genetic Systems, N.V., a predecessor of both Aventis and Bayer, developed a way to genetically engineer plants to produce a truncated version of that protein and obtained the four patents in suit relating to that invention. The first, U.S. Patent No. 5,545,565 (“the ’565 patent”), is directed to chimeric genes having a DNA fragment encoding a truncated insecticidal protein. The second, U.S. Patent No. 5,567,372 (“the ’372 patent”), is also directed to chimeric genes as well as plant cells and plants that produce the insecticidal protein. The third, U.S. Patent No. 6,106,546 (“the ’546 patent”), is directed to methods of protecting plants by altering the plants’ genetic codes so that they produce the insecticidal protein. The fourth, U.S. Patent No. 5,254,799 (“the ’799 patent”), is directed to plants and cells that produce the insecticidal protein. All four patents are related, the first three being the product of divisional applications of the application that ultimately matured into the ’799 patent.

As described in the largely overlapping specifications of the four patents, the invention took advantage of a known system for introducing foreign DNA into a plant cell’s genome by using the bacterium Agrobacterium tumefaciens (“Agrobacterium”), which has the natural capacity to transform the genome of certain plants. The specification describes a process starting with plant cells that are susceptible to genetic transformation by Agrobacterium. The Agrobacterium is then transformed so that its genome contains a chimeric gene comprising a DNA fragment that encodes a truncated form of the Bt insecticidal protein. The transformed Agrobacterium is then used to modify the plant cell’s genome so that the plant cell will express an insect-controlling amount of the Bt polypeptide toxin.

Monsanto sells genetically altered corn seeds that produce corn that expresses a Bt toxin at insecticidal levels. After Monsanto filed this action for declaratory relief and Aventis filed its counterclaim, Monsanto filed motions for summary judgment requesting that the four patents in suit be held unenforceable, invalid, and not infringed.

The district court granted Monsanto’s summary judgment motions. With respect to the broadest motion, the court held all four of the patents unenforceable because of inequitable conduct during the prosecution of the parent application that led to the issuance of the four patents. In addition, the court held that the collateral estoppel effect of a prior decision on a similar patent required the court to hold

that all of the asserted claims of the '546 patent and two of the asserted claims of the '372 patent were invalid, and that Monsanto did not infringe any of the asserted claims of the '799 patent. Finally, based on its construction of the claim term "Bt2," the court held that Monsanto was entitled to summary judgment of noninfringement as to all of the asserted claims of the '565 patent and one of the asserted claims of the '372 patent.

Bayer appeals from each of those three rulings. We hold that the district court improperly granted summary judgment on Monsanto's inequitable conduct claim, on its collateral estoppel claim, and on its noninfringement claim based on the construction of the claim term "Bt2." Accordingly, we reverse the summary judgment against Bayer and remand for further proceedings.

II

A

The district court granted summary judgment for Monsanto on the issue of inequitable conduct based on what the court concluded was a false declaration filed with the Patent and Trademark Office ("PTO") during the prosecution of the '799 patent. The court ruled that the false declaration rendered all four of the patents in suit unenforceable.

During prosecution, the examiner rejected certain claims as not being enabled. The examiner pointed out that the claims were directed to a truncated Bt gene for an insecticidal protein expressed in any plant, even though in the examiner's view the specification enabled the gene only in tobacco plants. To overcome that rejection, the applicants submitted a declaration by entomologist Stefan Jansens, an employee of Bayer's predecessor, Plant Genetic Systems, N.V., the assignee of each of the applications at issue in this case. In the declaration, Mr. Jansens attested that "any truncated Bacillus thuringiensis ('Bt') gene could be expressed in generally any plant to provide an insect controlling amount of its encoded Bt polypeptide toxin in the so-transformed plant as disclosed in this application" Along with his declaration, Mr. Jansens presented the results of tests conducted under his supervision. In addition, he attested that he knew of "no test results which are contrary to or inconsistent with the test

results [submitted to the PTO] or which would lead to different conclusions from those expressed” in the declaration.

In the district court proceedings, Monsanto sought summary judgment on its inequitable conduct claim, arguing that Mr. Jansens was aware of test results that were inconsistent with the statements in his declaration and that he intentionally withheld those test results from the PTO.

Bayer responded to Monsanto’s summary judgment motion by submitting an affidavit from Mr. Jansens in which he explained why he did not submit the allegedly inconsistent test results to the PTO. Mr. Jansens attested that the unsubmitted test results were not inconsistent with his representations during prosecution, because the purportedly negative results in those tests were actually inconclusive for various reasons. With respect to several of the tests, he explained that the data provided an insufficient basis from which to draw any reasonable conclusion as to whether the invention worked in the types of plants being tested. Moreover, he asserted that in some of the tests that did not show lethal levels of toxin production, the results showed growth inhibition in the target insects, which was consistent with the representations in his declaration that the invention could be made to work in plants generally and that he was aware of no test results supporting the contrary conclusion.

Mr. Jansens analyzed each of the test results cited by Monsanto and explained why the results in each case were not contrary to his declaration. In the case of the experiments on cotton plants, he explained, the level of mortality and growth inhibition for insects on the control plants was too high to allow a reasonable interpretation of whether there was an insect-controlling amount of Bt protein produced in the plants transformed with a Bt gene. Nonetheless, he added, despite the high background level of mortality in the controls of many of the cotton tests, some of the tests on cotton plants transformed with a truncated Bt gene still showed insect growth inhibition, indicating the possible production of insect-controlling amounts of Bt toxin.

With respect to the tests on plants of the Brassica genus (including cabbage), Mr. Jansens asserted that only a limited number of tests were run on those plants and that most of the results from those tests were insufficient to draw any reasonable general conclusion as to the transformed plants’

capacity to express the Bt toxin. Nonetheless, as in the case of the experiments on cotton plants, Mr. Jansens explained that data from several of the tests on Brassica plants showed insect growth inhibition.

Mr. Jansens further explained that only a limited number of tests were performed with potato and corn plants, and that the data from those tests did not provide a sufficient basis from which to draw any reasonable scientific conclusions. Once again, however, he noted that the tests on the transformed potato plants showed insect growth inhibition, indicating the possible production of insect-controlling amounts of Bt toxin. As to Monsanto's allegation that an experiment involving a single transformed tomato plant failed to show that truncated Bt genes conferred insect control in tomato plants, Mr. Jansens stated that other tomato plants transformed with the same truncated Bt gene were shown to be lethal to the same target insect.

More generally, Mr. Jansens explained that to obtain a plant transformed with a truncated Bt gene that expresses an insect-controlling or lethal amount of a truncated Bt protein,

it is well known that a large number of independently transformed plants must be obtained (in some cases using a variety of different gene constructs) and analyzed. If sufficient plants are obtained and then evaluated in an insect bioassay, from my experience, some plants might be lethal to the target insect, some might inhibit the growth of the target insect, and some might appear to have no effect on the target insect.

As is understood by persons working in the field, he added, "it is not reasonable to draw scientific conclusions from the experimental results on only a limited number of transformed plants, including whether or not a particular truncated Bt gene could be expressed in the particular plant to provide an insect-controlling amount of its encoded Bt polypeptide toxin in the so-transformed plant."

Accordingly, Mr. Jansens asserted that he believed his PTO declaration was accurate and that he had no intention to deceive the examiner or the PTO.

Notwithstanding Mr. Jansens' affidavit, the district court concluded that the omission of the test results cited by Monsanto rendered Mr. Jansens' PTO declaration false and misleading. The court further concluded that the false and misleading features of the declaration were material because the omitted test results would have been "highly important to a reasonable examiner." Finally, the court

concluded that the test results were so plainly material that the submission of the declaration by itself provided a sufficient basis for inferring that Mr. Jansens intended to deceive the PTO. Accordingly, the court entered summary judgment for Monsanto and held that each of the patents in suit was unenforceable due to inequitable conduct.

B

To hold a patent unenforceable for inequitable conduct, a court must find, by clear and convincing evidence, that the applicant omitted or misrepresented material facts with the intention of misleading or deceiving the patent examiner. See Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1048 (Fed. Cir. 1995); Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1261 (Fed. Cir. 2001); Upjohn Co. v. Mova Pharm. Corp., 225 F.3d 1306, 1312 (Fed. Cir. 2000). Once the challenger has shown the requisite levels of materiality and intent, the district court must balance the equities to determine whether the patentee has committed inequitable conduct that warrants holding the patent unenforceable. See Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1359 (Fed. Cir. 2003).

With respect to the issue of falsity, Monsanto argues that the district court correctly concluded that Monsanto presented “overwhelming evidence of negative results for other plant species that Jansens did not mention” and hence Mr. Jansens’ assertion in his declaration that he knew of no contrary test results was false. Bayer, on the other hand, relies on Mr. Jansens’ district court affidavit as evidence that the omitted test results were not “negative” with respect to the question that the patent examiner was seeking to answer. Instead, according to Bayer, the evidence showed that those tests led to no reliable conclusion. For that reason, Bayer argues, Mr. Jansens’ failure to refer to those tests in his PTO declaration was not misleading, and his statement that he knew of no scientific evidence contrary to the assertions in his declaration was not false.

In determining that the omitted test results were “contrary to the positive test results Bayer experienced with other species,” the district court necessarily discounted the affidavit in which Mr. Jansens explained the nature of those test results and their relationship to the conclusions set forth in his PTO declaration. In so doing, the court erred. On summary judgment, “[t]he evidence of the

nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). The district court, however, resolved the central dispute over the omitted test results in favor of Monsanto, a decision that required the court to reject the explanation provided in Mr. Jansens’ affidavit. If the court were to credit Mr. Jansens’ affidavit, it could find that the test results withheld from the PTO were not negative and that Mr. Jansens’ statement to the PTO that he knew of no contrary results was true. Thus, there is a factual dispute about the truth of the PTO declaration that should not have been resolved on summary judgment.

Monsanto argues that Mr. Jansens’ affidavit does not create a genuine issue of fact as to falsity because it is inconsistent with his deposition testimony. Monsanto asserts that at his deposition Mr. Jansens was asked why he did not submit the omitted test results to the PTO, and that he provided no answer. However, it is a disputed question of fact as to whether Mr. Jansens’ affidavit and his deposition testimony are inconsistent. At his deposition, Mr. Jansens was asked whether he submitted the test results in question. He admitted he had not submitted those results. When asked whether he thought he should have submitted them, he replied that as an entomologist it was difficult for him to determine what information the patent office would want. On remand, the district court may consider, in light of all the evidence, whether there is conflict between Mr. Jansens’ statements at his deposition and the statements in his affidavit, and if so, whether and to what extent his affidavit should be discounted as a result of the conflict.

Citing Paragon Podiatry Laboratory, Inc. v. KLM Laboratories, Inc., 984 F.2d 1182 (Fed. Cir. 1993), Monsanto argues that Mr. Jansens’ district court affidavit was conclusory and insufficient to raise a genuine issue of material fact as to falsity. In Paragon Podiatry, this court upheld a summary judgment of unenforceability. The court acknowledged that summary judgment of inequitable conduct should be rare, but that it is permissible on inequitable conduct, as on other issues, if there is no genuine issue of material fact. Id. at 1190. The court noted that “in looking to the record for evidence of a genuine issue . . . all of the circumstances, including those indicative of good faith, must be considered,” but that a genuine issue of material fact is not raised by the submission of “merely conclusory statements or completely insupportable, specious, or conflicting explanations or excuses.” Id.

Although Monsanto urges that we look to Paragon Podiatry as a template, Paragon Podiatry is markedly different from this case. In Paragon Podiatry, there was no question that the submission to the PTO was false and that the false representations were material; the only issue was whether the false and material representations were submitted with an intent to deceive. As to that issue, the court wrote that the affidavits submitted to explain the representations made to the PTO were “bare declaration[s] of lack of intent to mislead” and that the explanations provided in the affidavits were either “nonresponsive” or lacked evidentiary support. 984 F.2d at 1191-92. The court therefore concluded that the affidavits constituted nothing more than a conclusory denial, which is not sufficient to defeat a motion for summary judgment.

In this case, by contrast, the parties dispute not only the issue of intent, but also whether the declaration was false or misleading at all. Mr. Jansens’ affidavit described in detail each of the allegedly negative test results and explained why those test results, in Mr. Jansens’ view, were not inconsistent with the declaration he submitted to the PTO. Because Mr. Jansens’ affidavit sets forth a non-frivolous explanation that could lead a finder of fact to determine that his declaration was not false or misleading, the affidavit created a disputed issue of material fact as to whether the declaration was false or misleading.

Even if the court could conclude from the evidence in the summary judgment record that the omitted test results were contrary to the results the applicants achieved with other species, on remand the district court must still determine whether Monsanto has proved by clear and convincing evidence that the declaration was submitted with the intent to deceive the PTO. See Upjohn, 225 F.3d at 1312. While intent can sometimes be inferred from misleading conduct itself, see Paragon Podiatry, 984 F.2d at 1191, such an inference “is not required in every case, even when the misrepresentation is in affidavit form,” Glaxo, 52 F.3d at 1048.

We have explained that “[a]lthough the intent element of fraud or inequitable conduct may be proven by a showing of acts the natural consequence of which were presumably intended by the actor, this requires the fact finder to evaluate all the facts and circumstances in each case. Such an evaluation

is rarely enabled in summary proceedings.” Paragon Podiatry, 984 F.2d at 1190. In Paragon Podiatry, it was proper to infer intent when the patentee submitted admittedly false affidavits that “convey[ed] the impression of deliberate artfulness” by skirting the truth, and had the “natural consequence” of deceiving the examiner. Id. at 1191.

Unlike in Paragon Podiatry, Mr. Jansens did not simply offer a conclusory declaration of lack of intent to deceive. His assertion that he did not intend to deceive the PTO was based on his detailed explanation of his interpretation of the disputed test results. Thus, this case satisfies the requirement described in Paragon, that the affiant who seeks to avoid summary judgment “must at least state facts supporting a plausible justification or excuse for the misrepresentation.” 984 F.2d at 1191. It was therefore improper for the district court on summary judgment to infer an intent to deceive based on the court’s conclusion that the declaration was false and that the explanation for the falsity was unpersuasive. To show intent to mislead, Monsanto must show by either direct or indirect evidence that when Mr. Jansens attested that he knew “of no test results which are contrary to or inconsistent with the test results [submitted to the PTO] or which would lead to different conclusions from those expressed” in the declaration, he knew the statement was false or misleading.

The district court also found that the circumstances surrounding the declaration provided convincing evidence that Mr. Jansens’ declaration was submitted with the intention of misleading the PTO. In particular, the court pointed to the threat that without the declaration the examiner would limit the claims to tobacco plants, and focused on Aventis’s status as a “small enterprise with limited resources . . . pursuing a survival strategy.” The circumstances surrounding the submission of the declaration are certainly relevant to the inquiry into intent, which ordinarily cannot be established by direct proof and must be inferred from an assessment of all the surrounding circumstances. See Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422 (Fed. Cir. 1989). But the small size of the applicants’ company and the applicants’ presumed incentive to obtain broad patent protection for their inventions did not give rise to such a compelling inference of deceptive intent as to justify the entry of summary judgment on that issue.

In sum, because the parties' submissions in the summary judgment proceedings created a genuine issue of fact as to whether Mr. Jansens' declaration was false or misleading and whether Mr. Jansens intended to mislead the PTO, we hold that summary judgment of unenforceability was improper. On remand, the district court must weigh all of the evidence, direct and circumstantial, to determine whether Mr. Jansens' declaration was false or misleading, and whether he intended to deceive the examiner.

III

The district court entered a second summary judgment order giving collateral estoppel effect to a decision in an earlier case between the predecessors of the parties in this case, Plant Genetic Systems, N.V. v. DeKalb Genetics Corp., 175 F. Supp. 2d 246 (D. Conn. 2001), aff'd, 315 F.3d 1335 (Fed. Cir. 2003). The district court viewed the Plant Genetic Systems case as establishing that corn was not susceptible to transformation by Agrobacterium as of the priority date for the patents at issue in this case. Based on that characterization, the court concluded that collateral estoppel principles required it to hold that the asserted claims of the '546 patent and claims 13 and 18 of the '372 patent were invalid for lack of enablement and that the asserted claims of the '799 patent were not infringed.

The patent in suit in the Plant Genetic Systems case claimed the use of Agrobacterium to transform plants by inserting the "bar" gene, which would increase the plant's resistance to certain herbicides, so that a farmer who sprayed a field with the herbicide would be able to kill all the unwanted plants but leave the transformed plants unaffected. The district court in that case held that the patent enabled the transformation of dicotyledonous ("dicot") plants but not monocotyledonous ("monocot") plants, although the claim language was broad enough to cover both. 175 F. Supp. 2d at 257. Not finding adequate disclosure in the specification, the court examined evidence presented by Bayer's predecessor concerning the knowledge of one skilled in the art as of 1987, the filing date for the patent in that case. Id. at 257-65. In particular, the court noted that the evidence at trial revealed that no one was able to use Agrobacterium to create a successful transformation method for monocots until several years after 1987. Id. at 261. Accordingly, the court ruled that several of the asserted claims were not

enabled and that the remainder had to be construed to be limited to dicots, and not to cover monocots such as corn. Id. at 265, 270.

The district court in this case explained that because Bayer's predecessor had litigated and lost on the question whether corn could be genetically transformed by Agrobacterium as of 1987, Bayer could not now argue that corn could be genetically transformed by that means as of 1986, the priority date for the patents at issue in this case. Because both parties in this case agreed that the asserted claims of the '546 patent and claims 13 and 18 of the '342 patent cover monocots as well as dicots, the court held that Bayer was barred from arguing that those claims were fully enabled. Moreover, in light of the evidence regarding the state of the art in 1987, the court in the Plant Genetic Systems case construed the phrase "susceptible to transformation by Agrobacterium" as limited to dicots. Based on that ruling, the court in this case held that the same phrase in the '799 patent had to be construed in the same way and that, as a consequence, Monsanto's corn products did not infringe any of the asserted claims of the '799 patent.

What the court decided in Plant Genetic Systems was that the specification of the patent in that case did not enable the insertion of the bar gene into monocots and that the transformation of a monocot was not within the skill of ordinary artisans without the need for undue experimentation as of the filing date of that patent. See, e.g., 175 F. Supp. 2d at 255 ("In this case, one of the central questions addressed at trial was whether any methodology existed as of this date by which the bar gene could be stably integrated into monocots."); id. at 265 ("In March of 1987, a person skilled in the art who attempted to stably integrate the bar gene into plants cell [sic] other than dicots would have had to engage in undue experimentation—assuming that they could have successfully completed the task at all. Further, this deficiency is not cured by the specification."); id. at 264 ("The plain import of such evidence is that a significant amount of experimentation was necessary to be able to stably insert a heterologous DNA fragment into a monocotylenous [sic] plant cell in early 1987 . . . [and] the patent itself provided little guidance to others who want to practice the full scope of its inventions."). On appeal, this court confirmed that the cell claims of the patent were not enabled by the specification and that "practicing stable gene transformation for monocot cells in 1987 required undue experimentation."

315 F.3d at 1338. Accordingly, we upheld the district court's ruling that certain claims of the patent at issue were invalid for lack of enablement and others had to be construed as limited to dicot plants.

The two questions that the district court in this case held to be governed by collateral estoppel were (1) whether the specifications of the '546 and '372 patents fail to enable the inventions with respect to monocots, and (2) whether the claims of the '799 patent must be construed to be limited to dicots. Those questions are similar to the issues decided in the Plant Genetic Systems case, but they are not the same.

In order to determine whether the specifications of the '546 and '372 patents enable the transformation of monocots through the use of Agrobacterium, the district court must consult those specifications, which differ significantly from the specification of the patent at issue in the Plant Genetic Systems case. Bayer does not dispute that the parties in Plant Genetic Systems fully litigated the issue of whether one of ordinary skill in the art in 1986 would be able to transform a monocot using Agrobacterium.^[1] For that reason, if Monsanto succeeds in showing by clear and convincing evidence that the specifications of the '546 and '372 patents do not teach one of ordinary skill how to transform a monocot with a gene for a Bt toxin, Bayer would be precluded by Plant Genetic Systems from arguing that one of skill in the art in 1986 would already have known how to perform such a transformation. Thus, collateral estoppel may bear on the enablement issue, but only if the district court concludes that the specifications of the '546 and '372 patents themselves do not teach the transformation of monocots.

In order to determine whether the claims of the '799 patent must be construed to be limited to dicots, the court must consult the intrinsic evidence relating to the '799 patent, which was not at issue in the Plant Genetic Systems case. It is not enough for the court simply to rely on the conclusion of the court in Plant Genetic Systems that the prosecution history of the patent in that case and the corresponding extrinsic evidence support a narrow construction of the term "susceptible to transformation by Agrobacterium," because similar terms can have different meanings in different patents depending on the specifics of each patent.

The court in Plant Genetic Systems did not determine that the state of the art in 1987 alone

compelled a construction of the phrase “susceptible to transformation by Agrobacterium” to exclude monocots. Rather, the court construed the term “susceptible to transformation by Agrobacterium” as limited to dicots based primarily on the intrinsic evidence, in particular the prosecution history of the ’236 patent. 175 F. Supp. 2d at 268; accord 315 F.3d at 1345 (“[B]ased on the prosecution history alone, the claims at issue [of the ’236 patent] cannot cover corn or any other monocots.”). The court then continued by analyzing the extrinsic evidence, which it concluded supported such a construction, since “[a] person skilled in the art would have been aware of this limitation . . . and would understand the wording of the plant and seed claims to mean that they did not cover monocots such as corn.” 175 F. Supp. 2d at 269; accord 315 F.3d at 1346 (“Having so determined, the district court consulted extrinsic evidence to ensure that its interpretation of the claim language was not inconsistent with the understanding in the technical field as of the filing date of the patent.”). Because the district court in Plant Genetic Systems construed the term “susceptible to transformation by Agrobacterium” based principally on evidence specific to the patent at issue in that case, Bayer should not now be precluded from arguing that the same claim term appearing in the claims of the ’799 patent has a different meaning.

Moreover, the intrinsic evidence for the ’799 patent supports a construction that encompasses monocots. The specification, for example, states:

The present invention contemplates that the hybrid plasmid transformation vectors may be used to develop plant cells and their progeny exhibiting insect resistant properties. It is contemplated that plants, particularly dicotyledonous plants, other than those described below in the examples can be transformed such as cotton, sugarbeet, soybean, rape and vegetables such as cabbage, lettuce and beans.

’799 patent, col. 11, ll. 60-67. Although the specification emphasizes the transformation of dicots, the manner in which the patent refers to dicots (“particularly dicotyledonous plants”) may imply that monocots are also within the scope of the invention. The prosecution history also provides support for the broader claim construction. During the prosecution of the application that led to the ’799 patent, the examiner rejected the application on the ground that the specification did not enable the transformation of plants other than dicots. In overcoming that rejection, the applicants stated that “applicants have not limited their claimed plants, seeds, and tissues to dicotyledons because it is believed that such a

limitation is unnecessary. In this regard, at least three monocots (i.e., Asparagus, Liliaceae and Amaryllidaceae) were known to be transformable with a Ti-plasmid from Agrobacterium at the time this application was filed.” It was therefore improper for the district court to apply the claim construction in the Plant Genetic Systems case without examining the intrinsic evidence specific to the ’799 patent.

IV

Finally, based on its construction of the claim term “Bt2,” the district court ruled that all of the asserted claims of the ’565 patent and claim 4 of the ’372 patent are not infringed. The court determined that the reference to “Bt2” was limited to a strain of Bt obtained from a particular source, the berliner 1715 strain of Bt, and that the term “Bt2 toxin” was therefore limited to a protein derived from that strain. For that reason, the district court determined that an identical protein derived from a different strain of Bt would not infringe. Because the court determined that the toxin produced by Monsanto’s corn is derived from a different strain of Bt, it granted summary judgment of noninfringement on the claims reciting the “Bt2 toxin” or “Bt2 crystal protein.”

Claim 1 of the ’565 patent includes the term “Bt2 toxin” and is representative of the claims at issue:

1. A chimeric gene comprising:

(1) a DNA fragment encoding an insecticidal *Bacillus thuringiensis* Bt2 toxin of about 60 to about 80 kD, wherein said Bt2 toxin comprises the amino acid sequence of SEQ ID No. 1 from amino acid position 29 to amino acid position 607; and

(2) a promoter region of a gene naturally expressed in plant cells, wherein said DNA fragment is under the control of said promoter region.

Unlike claim 1 of the ’565 patent, claim 4 of the ’372 patent, which includes the claim term “Bt2 crystal protein,” does not on its face limit the protein to a specific amino acid subset of “SEQ ID No. 1.”

The claims of the ’565 patent define a “Bt2 toxin” as a molecule of a molecular weight of about 60 to about 80 kD comprising a particular amino acid sequence. The claims do not limit the “Bt2 toxin” to toxins from the berliner 1715 strain of Bt. Instead, any toxin complying with the molecular weight

and amino acid sequence requirements of the claims would satisfy the ordinary meaning of the claims.

Monsanto argues that, notwithstanding the breadth of the claim language, the specification of the '565 patent, at columns 3 through 6, limits the "Bt2 toxin" to the berliner 1715 strain of Bt because it contrasts the protein encoded by a gene from the berliner 1715 strain of Bt, the "Bt2" gene, with similar proteins encoded by other strains of Bt. The district court similarly found that Figures 14A through 14C of the '565 patent indicated that the Bt2 toxin was limited to proteins encoded by genes derived from the berliner 1715 strain. The cited portions of the '565 specification, however, do not limit the "Bt2 toxin" to a particular source. Instead, they simply show that proteins expressed by genes from the berliner 1715 strain have the claimed structure, while proteins expressed by genes derived from other strains of Bt may have structures different from the "Bt2 toxin." That is not the same as saying that the term "Bt2 toxin" is defined by its source rather than by its structure.

The district court also relied on column 22, lines 31-35, of the '565 patent as supporting its claim construction. That passage, however, merely states that the Bt2 toxin can be produced using the Bt2 gene. The passage then refers to another portion of the specification in which the Bt2 toxin is described by reference to its amino acid sequence ('565 patent, col. 19, l. 58, through col. 20, l. 38). These and other passages from the '565 patent cited by Monsanto and the district court describe a way to obtain the Bt2 toxin using the Bt2 gene, but they do not suggest that the Bt2 toxin is defined by its source rather than by its chemical structure, nor do they suggest that a substance derived from a different source cannot fall within the definition of Bt2 toxin.

Monsanto next argues that during prosecution the applicants gave up any claim to toxins derived from a source other than the berliner 1715 strain of Bt. In the course of the prosecution, the examiner rejected claims to a gene comprising "a first DNA fragment that encodes an N-terminal fragment of approximately 60-80 kd, derived from DNA encoding a Bacillus thuringiensis [Bt] insecticidal crystal protein," based on lack of enablement. The examiner concluded that the specification failed to show how the Bt protein was truncated and that the specification enabled only the protein sequence shown in Figure 13 of the patent. The applicants cancelled the claims in question and added new claims that

included the limitation “a DNA sequence encoding a Bacillus thuringiensis Bt2 toxin, wherein said Bacillus thuringiensis Bt2 toxin is a trypsin-digested Bt2 protein of SEQ. ID No. 1” The examiner again rejected the claims for failing to designate specific portions of the sequence “SEQ. ID No. 1.” The applicants cancelled the claims again and added claims that included the limitation “a DNA fragment encoding an insecticidal Bacillus thuringiensis Bt2 toxin of about 60 to about 80 kD, wherein said Bt2 toxin comprises the amino acid sequence SEQ. ID No. 1 from amino acid position 29 to amino acid position 607”

Monsanto argues that it was the inclusion of both “Bt2” and the sequence “SEQ. ID No. 1” that persuaded the examiner to allow the claims, and that the examiner thus allowed the claims only after the applicants specified the source of the toxin. It is clear from the prosecution history, however, that the examiner was persuaded to allow the claims only after the applicants identified the amino acid sequence of the full Bt2 protein and, in the case of the claims of the ’565 patent, the specific portion of the protein, from amino acid position 29 to amino acid position 607, that formed the Bt2 toxin. Thus, it was not the identification of a source, but rather the inclusion of the particular amino acid sequence of the toxin that persuaded the examiner to withdraw the rejections.

During prosecution, the applicants commented on the inclusion of the limitation “a DNA sequence encoding a Bacillus thuringiensis Bt2 toxin, wherein said Bacillus thuringiensis Bt2 toxin is a trypsin-digested Bt2 protein of SEQ. ID No. 1” They stated that their “new claims recite a Bacillus thuringiensis Bt2.” The district court found that by that statement the applicants acknowledged a source limitation in the claims. Although it is not clear what the applicants meant by the reference to “Bacillus thuringiensis Bt2,” the most reasonable interpretation of that comment is that they were explaining to the examiner that they had limited the claims by specifying a particular amino acid sequence. In any case, that passage does not clearly limit the “Bt2 toxin” to a particular source.

Because the claims define “Bt2” in terms of the molecular weight and amino acid sequence of the claimed toxin, and because neither the specifications of the patents at issue nor their prosecution histories suggest that the term must be limited to a toxin derived from a particular source, the district

court erred in its claim construction. The grant of summary judgment of noninfringement based on that claim construction was therefore erroneous. Accordingly, we reverse the district court's judgment on the claims affected by the "Bt2" claim construction issue, and we remand the case for further proceedings with respect to those claims and with respect to the issues addressed in Parts II and III above.

REVERSED and REMANDED.

[1] Bayer argues that the issue in Plant Genetic Systems was limited to the stable transformation of plants, and that the claims at issue in this case do not require stable transformation. In fact, however, the specifications of the patents in suit strongly suggest that the claims require stable integration. See, e.g., '372, '799, and '546 patents, Abstract ("Transformed plant cells and their progeny exhibit stably inherited polypeptide toxin expression useful for protecting said plant cells and their progeny against . . . insect pests and in controlling said insect pests."); '546 patent, col. 11, ll. 35-44; '372 patent, col. 11, l. 63-col. 12, l. 5; '799 patent, col. 11, l. 60-col. 12, l. 2 ("The present invention contemplates that the hybrid plasmid transformation vectors may be used to develop plant cells and their progeny exhibiting insect resistant properties. . . . Transformed plant cells and their progeny are protected against certain insect pests by expressing an insect controlling amount of polypeptide toxin."). In any case, Bayer raises this issue for the first time on appeal and has therefore waived the argument.